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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,829	04/18/2002	Christophe Beclin	34920-PCT-USA 072667.0179	2360

21003 7590 04/08/2004

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EXAMINER	
IBRAHIM MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,829	BECLIN ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-52* is/are pending in the application.

4a) Of the above claim(s) *36-43 and 50* is/are withdrawn from consideration.

5)☒ Claim(s) *32-35* is/are allowed.

6)☒ Claim(s) *23-28,30,31,44-49,51 and 52* is/are rejected.

7)☒ Claim(s) *29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election with traverse of Group I filed 01/21/04 is acknowledged. The traversal is on the ground(s) that Applicant submits that a relationship exists between the nucleic acid of Group I and its encoded polypeptide of Group II, and hence unity of invention exists between the two groups under PCT Rule 13. In the instant case, however, there is a lack of unity since there is no structural and functional relationship between the nucleic acid of Group I and the polypeptide of Group II. Under PCT rule 37 CFR 1.475(d), where multiple products such as nucleic acids (first product) and polypeptides (second product) are claimed, Applicant is entitled unity of invention between first product and the method of using and the method of making the product. In the instant application, Applicant is entitled unity between claims 23-35, 44-49 and 51-52. Claim 50, drawn a process of using the second product (the polypeptide of Group II) was inadvertently included in Group I. In addition, the special technical feature of Group I not recited in Group II is the nucleic acid sequences, expression vectors, and plants comprising said nucleic acid sequences, and a method of using said nucleic acid sequences. The special technical feature of Group II not recited in Group I is the isolated polypeptide and a method of using said polypeptide. Therefore, Applicant's arguments are not persuasive. Finally, Applicant makes an argument about criteria for proper restriction requirement, particularly the burden required to search the restricted groups. Applicant cites MPEP (800) to support this position. However, search burden is not a consideration under lack of unity requirements. Accordingly, for all the reasons

discussed above, Groups I-II lack unity of invention. Therefore, the requirement is still deemed proper and is therefore made FINAL.

2. Claims 23-52 are pending.

3. Claims 23-35, 44-49, and 51-52 are under consideration.

4. Claims 36-43 and 50 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 48-49 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is indefinite for failing to recite the specific hybridization and wash conditions for the desired DNA. Since hybridization conditions vary from one laboratory to another, one skilled in the art would know what is encompassed by the claims. Appropriate correction is required to more clearly define the metes and bounds of the claims.

Claims 48 and 49 are indefinite for failing to recite complete method steps that results in expression of heterologous gene. The claim recites a single step, contacting a host organism with the expression vector. In addition, it is unclear how a contact will induce an expression of a heterologous gene.

Claim Rejections - 35 USC § 101

7. Claims 47-49 and 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a process of transforming a "host organism" and a transformed "host organism" which read on process of transforming a human organism and a transformed human organism, respectively. Human organism is a non-statutory subject matter and cannot be patented.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 23-28, 30-31, 44-49 and 51-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleotide sequence of SEQ ID NO: 1 and 2 encoding SEQ ID NO: 3, expression vectors and a transformed plant comprising said nucleotide sequence, and a process of transforming a plant with said nucleotide sequence, does not reasonably provide enablement for isolated nucleotide sequences having at least 80%, 90%, 95%, 98%, and 99% homology to SEQ ID NO: 1 and 2, expression vectors, and any host organism comprising said sequences, and a process for transforming a host organism with said nucleotide sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims nucleotide sequences having at least 80%, 90%, 95%, 98%, and 99% homologous to SEQ ID NO: 1 and 2, and to nucleotides 1-695 of SEQ ID NO: 1. No function is recited for these sequences. Applicant also claims expression vectors and transformed host organisms comprising said nucleotide sequences. Applicant further claims a process for transforming a host organism or expressing a heterologous gene in a host organism with said nucleotide sequences.

Applicant teaches isolation and identification of cDNA and genomic sequences (SEQ ID NO: 1 and 2) involved in the post-transcriptional inactivation of transgene expression from Arabidopsis (Example 1). Applicant also teaches analysis of various sgs3 Arabidopsis mutants, and construction of expression vectors for plant transformation for the inhibition or overexpression of plant SGS3 genes (Examples 2 and 3). In Example 5, Applicant teaches inhibition of expression of the SGS3 gene with the antisense sequence of SEQ ID NO: 2. Applicant also teaches GUS activity of the p35S-GUS-tRbcS transgene was measured in plants transformed with p35S-aSGS3-t35S (shs3 mutants) and nontransformed plants. The GUS activity in the nontransformed was between 0 and 10 nmol/ Mu/min/ug of proteins, while the GUS activity in the transformed plants (sgs3 mutants) is between 3000 and 5500 nmol Mu/min/ug proteins, showing that the SGS3 plant gene may be inhibited by the chimeric gene. Applicant states that SEQ ID NO: 1 and 2 can be used in post-transcriptional inactivation in order to improve the stability of transgene expression in plants and in the resistance of plants to viral infections.

Applicant has not provided guidance for the obtention of the nucleotide sequences having less than 100% identity to the disclosed sequence or their role in post-transcriptional inactivation phenomena in transgenic plants, and in the resistance of plants to viral infections. Applicant has not provided guidance for the transformation of host organisms other than plants. Applicant has not taught how to use nucleotide sequences having at least 80%, 90%, 95%, 98%, and 99% homologous to SEQ ID NO: 1 and 2 having no known function. Assuming arguendo that nucleotide sequences having at least 80%, 90%, 95%, 98%, and 99% homologous to SEQ ID NO: 1 and 2 will retain the biological activity of the disclosed sequences, it is unclear how and where to modify the disclosed sequences so that nucleotide sequences having the structural properties as recited in the claims and still retaining the desired biological activity can be obtained. Applicant has not taught modifications to the disclosed sequences that retain the desired biological activity. Substantial guidance to determine regions in SEQ ID NO: 1 and 2 that are sufficient to inactivate SGS3 gene in plants, so that a stable expression of a desired gene can be obtained. Absent such guidance, one skilled in the art would have to proceed with trial and error experimentation considered undue. In addition, the working example disclosed in the specification is limited to the use of unmodified SEQ ID NO: 2. The specification is not enabled for a nucleotide sequence comprising nucleotides from 1-695 of SEQ ID NO: 1 having promoter activity because no regions/elements essential for promoter activity have been identified or evaluated. Therefore, claims that recite a nucleotide sequence comprising nucleotides from 1-695 of SEQ ID NO: 1 having promoter activity are not enabled.

In addition, the specific effects of given promoters, DNA sequences, and terminator sequences on gene expression in transformed plants cannot be anticipated reliably and must be determined empirically (Koziel et al. Plant Mol. Biol. 32:393-405, 1996, Abstract, pp. 402-403). In addition, the mechanisms of gene silencing are still not fully understood (Stam et al.; Ann.Bot. 79; 3-12, 1997 (Abstract, p. 9). Absent further guidance, undue experimentation is required to screen through a vast number of nucleotide sequences from various sources to determine those that are functionally related to SEQ ID NO: 1 or 2. Undue experimentation will also be required to screen through the myriad of different DNA constructs and the vast number of transgenic plants to determine how to stabilize expression of any heterologous gene in a transgenic plant and/or induce resistance to viral infection.

Therefore, given the breadth of the claims; the lack of sufficient guidance from the specification or the prior art; the limited working examples in the specification; the nature of the invention; unpredictability inherent regarding gene silencing; and the state of the prior art, the claimed invention is not enabled throughout the broad scope. See In re Wands 858 F.2d 731, 8USPQ2nd 1400 (Fed. Cir, 1988). See, also, *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

10. Claims 23-28, 30-31, 44-49 and 51-52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to nucleotide sequences having at least 80%, 90%, 95%, 98%, and 99% homologous to SEQ ID NO: 1 and 2, and to nucleotides 1-695 of SEQ ID NO: 1. No function is recited for these sequences. Applicant also claims a nucleotide sequence comprising nucleotides 1 to 695 of SEQ ID NO: 1 having promoter activity. However, Applicant has not described regions/sequences essential for promoter activity. Applicant further claims a process for transforming a host organism or expressing a heterologous gene in a host organism with said nucleotide sequences, and expression vectors and transformed host organisms comprising said nucleotide sequences. In contrast, Applicant describes SEQ ID NO:1 and 2 encoding SEQ ID NO: 3, plants transformed with said sequences and a process of transforming plants with said sequences. These are genus claims.

University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from

that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The claimed invention does not meet the current written description requirements for the following reasons: firstly, the claims do not recite functional limitation for the DNA sequences. Secondly, Applicant has not described a representative number of nucleotide sequences of the genus claims. Thirdly, Applicant has not described structural features common to all the members of the genus claimed, which would allow one to predictably determine the identity of the species of the claimed genus. Therefore, the specification fails to adequately describe the nucleotide sequences as broadly claimed. Consequently, the specification has not provided an adequate description for expression vectors and host organisms comprising said nucleotide sequences, and methods that employ said nucleotide sequences. Given this lack of description of representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that Applicant was in possession of the invention as broadly claimed at the time of filing. See, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Remarks

The claims are deemed free of the prior art of record.

Claims 32-35 are allowed.

Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and After final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Mai
4/4/04